AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

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May 27, 2014

Via Electronic Mail: oira_submission@omb.eop.gov

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer
FAX: 202-395-6974

Re: The Food and Drug Administration Deems Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warnings for Tobacco Product Packages and Advertisements; Docket No. FDA-2014-N-0189; RIN 0910-AG38

Dear Sir or Madam:

The American E-Liquid Manufacturing Standards Association (AEMSA) appreciates this opportunity to respond to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) request for comments on the information collection provisions in the Food and Drug Administration's (FDA's) Notice of Proposed Rulemaking (NPRM) for the "Deeming Regulation" (Docket No. FDA-2014-N-0189; RIN 0910-AG38), which proposes to deem currently unregulated tobacco and nicotine-containing products as regulated tobacco products pursuant to the Food, Drug and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (the Tobacco Control Act).[1] In accordance with the Paperwork Reduction Act of 1995 (the PRA), the purpose of this letter is to provide AEMSA's responses to the requests for comments on the information collection provisions of the NPRM. Specifically, as required by the PRA, you have requested comments with regard to the following: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to

[1] *See* 79 Fed. Reg. 23,142 (April 25, 2014).

enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

I. AEMSA Comments on Behalf of its Members of the Refillable E-Liquid Industry

AEMSA is the first and only manufacturers' trade association completely dedicated to creating responsible and sustainable standards for the safe manufacturing of "e-liquids" used in electronic cigarettes (e-cigarettes). AEMSA is an all-volunteer organization, formed by American manufacturers of e-liquids, to promote safety and responsibility through self-regulation. Our members believe we have a responsibility to self-regulate the e-liquid manufacturing process based on professional criteria. Indeed, one of AEMSA's primary goals is to provide consumers with higher degrees of confidence that our members' products are manufactured with professionalism, accuracy and in a safe manner until such time as FDA promulgates Good Manufacturing Practices for e-liquids. In this regard, AEMSA has developed manufacturing standards for of e-liquids, which may be downloaded from our website at: http://www.aemsa.org/standards/. AEMSA supports reasonable, responsible and science-based regulation of electronic cigarettes, including Advanced Refillable Personal Vaporizers (ARPVs) and the refillable e-liquids used in those products.

In order to obtain OMB approval of the massive information collection requirements proposed in the NPRM, FDA is obligated to "demonstrate that it has taken every reasonable step" to ensure that these information collections comply with the substantive standards established by the PRA.[2] A key element of the process by which FDA evaluates whether it can certify such compliance is the required solicitation of public comment regarding the proposed collections. This mandatory public consultation process is intended, *inter alia*, to allow interested parties to review and comment on not only "the accuracy of the FDA's estimate of the burden of the proposed collection of information," but also "the validity of the methodology and assumptions used" by FDA in formulating such estimates.[3] The public comment period also is required in order to give interested parties an opportunity to offer their informed judgments regarding the necessity and practical utility of the proposed collections and to offer meaningful suggestions for reducing the burdens of these collections and enhancing their quality, utility and

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[2] *See* 5 C.F.R. § 1320.5(d)(I).

[3] *Id.*, § 1320.8(d)(1)(ii).

clarity.[4] For this reason, AEMSA is providing these comments to OMB on behalf of its manufacturing members of the rapidly growing refillable e-liquid industry who, if the NPRM becomes effective as drafted, will be considered tobacco product manufacturers under the Tobacco Control Act.

II. Request for Extension of Comment Period Deadlines

AEMSA is in the process of preparing detailed comments in response to FDA's numerous requests in the NPRM, including the information collection issues under the PRA. We are, however, very concerned that we will not be able to adequately respond to those requests by either the May 27, 2014 deadline for these PRA comments, or the by July 9, 2014 deadline for all general comments. There are over 50 separate requests for comments in the proposed rule that AEMSA is considering responding to on behalf of its members in the refillable e-liquid industry. Many of these requests for comments require obtaining, summarizing and providing supporting scientific research and other evidence. Neither the 32-day period for the PRA comments, nor the 75-day period for the general comments, allows sufficient time to develop meaningful or thoughtful responses to the questions raised in the proposed rule. Specifically, with respect to the PRA questions, additional time is needed to gather information on the number of (1) e-cigarette and e-cigarette component companies (*i.e.*, e-liquid companies, "vape" shops and ARPV hardware manufactures) that could potentially be considered tobacco product establishments in the United States, and (2) unique e-liquid formulations that would be considered tobacco products subject to the Tobacco Control Act's product and ingredient listing and premarket authorization requirements, among other things, once the NPRM becomes effective.

Accordingly, we respectfully urge the Agency to extend each comment period by, at the very least, an additional 105-days (so that PRA comments would be to OMB due by September 9, 2014 and the general comments to FDA by October 22, 2014), to provide ample time for stakeholders to gather the necessary information and provide constructive feedback on the issues raised in the proposed rule. We do not believe that such an extension would significantly delay any potential regulatory action on these important issues, and can only aid in providing FDA with the information that it needs to regulate the growing refillable e-liquid industry in a responsible manner.

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[4] *Id.*, § 1320.8(d)(1)(i), (iii).

III. E-Cigarette and E-Liquid Products Should Not Be Regulated as Tobacco Products

For purposes of these comments on the Paperwork Reduction Action implications of the proposed information collections, we assume, *arguendo*, that e-cigarette and e-liquid products will be "covered tobacco products" subject to the Tobacco Control Act requirements, which currently only apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, if the NPRM becomes effective. AEMSA's position, however, is that e-cigarette and e-liquid products should *not* be regulated as conventional tobacco products, but rather that FDA should use its enforcement discretion to regulate products that only contain tobacco-derived substances (*i.e.*, nicotine) differently than conventional products that actually contain tobacco (*e.g.*, cigarettes, smokeless tobacco and roll-your-own tobacco). To support such use of the Agency's enforcement discretion, we note that, among other reasons:

a. Congress Intended FDA to Use its Discretion to Establish Appropriate Regulatory and Paperwork Burdens for Other Tobacco Products Deemed to be Regulated by the NPRM

There is much evidence to indicate that Congress did not intend for nicotine-only products to be subject to the same regulatory requirements as tobacco-containing products. Electronic cigarettes were not on the U.S. market, or were just entering the market, when the Tobacco Control Act was being debated in Congress. Indeed, nowhere in the Act's legislative history is there any mention of such novel products. Although a tobacco product is defined broadly in the Act, Congress only granted FDA immediate authority to regulate tobacco products that contain tobacco (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco), while allowing the Agency to *not* regulate other tobacco products. This suggests that, with respect to tobacco products deemed to be regulated, Congress actually intended FDA to use its discretion to impose appropriate regulatory requirements tailored to the type of deemed tobacco product in question.[5] In other words, it is possible that the regulatory scheme in the Tobacco Control Act that currently applies to cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco may be the appropriate scheme for deemed products that actually contain tobacco (e.g., cigars and pipe tobacco), but not for deemed products that only contain tobacco-*derived* substances, like e-cigarettes. For those novel products, FDA should establish appropriate regulatory procedures with paperwork burdens commensurate with the harm that requires regulation.

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[5] Indeed, FDA has proposed an "Option 2" in the NPRM (discussed below) whereby it would exempt premium cigars – a combustible product with known health consequences – from the Tobacco Control Act requirements.

Moreover, applying the same regulatory requirements to nicotine-only products that have the ability to help smokers transition to less harmful forms of nicotine will result in most such products being removed from the market, which would be contrary to the stated purpose of the Tobacco Control Act. Specifically, when Congress passed the Tobacco Control Act it set out ten purposes underlying the legislation. These purposes included not only reducing "the social costs associated with tobacco-related diseases" and ensuring "that consumers are better informed"—but also continuing "to permit the sale of tobacco products to adults" and providing effective oversight of the "industry's efforts to develop, introduce, and promote less harmful tobacco products."[6] If the NPRM is implemented as drafted, most e-cigarette and e-liquid products would be eliminated from the market because of the very high regulatory and paperwork burdens. This would clearly go against Congress' intent to reduce harm from tobacco-related disease through the promotion of less harmful products. The evidence suggests that Congress understood that the Tobacco Control Act was not intended to bring the tobacco industry to a grinding halt; rather, it sought only to establish "appropriate regulatory controls" over tobacco products.[7] FDA should take a similar approach in the Deeming Regulation to establish appropriate regulatory controls over e-cigarette and e-liquid products based, for example, on where the deemed tobacco product falls on the "continuum of risk" for tobacco products.

b. FDA Should Recognize the "Continuum of Risk" When Imposing Regulations on Deemed Tobacco Products

To reduce the paperwork burdens of the proposed rule, FDA should revise the information collections to more appropriately reflect the realities of e-cigarette and e-liquid companies, and to take into consideration the public health impact of products that only contain tobacco-derived substances (*e.g.*, nicotine), compared to those that contain or combust tobacco. While the Tobacco Control Act broadly defines a "tobacco product" to include substances that are derived from tobacco, products that only contain such tobacco-derived substances should not be regulated in the same manner as products that contain tobacco *per se* (*e.g.*, cigarettes, smokeless tobacco and roll-your-own tobacco). In this regard, FDA should recognize – and incorporate into their regulations – the wide disparity of risk posed by different types of nicotine-containing products. This risk disparity can be described on a "continuum of risk," whereby the product that poses the greatest harm and risk of tobacco-related disease (*i.e.*, the traditional, combustible cigarette) is on one end of the continuum, and that new product forms that do not contain or combust tobacco are on the other end. Tobacco-containing products, especially those that are combusted (cigarettes), are the most harmful and dangerous products on the continuum

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6 *See* 21 U.S.C. 387 et seq.

7 *Id.*

of risk and should be treated as such. It is well established, for example, that the more pyrolyzed tobacco constituents a user inhales from a combustible tobacco product, such as a cigarette, the greater the risk of tobacco-related disease that product poses.[8] Of the approximately 5,300 chemicals identified in tobacco smoke, at least 60 are known human carcinogens, including polycyclic aromatic hydrocarbons (PAHs) and tobacco-specific nitrosamines (TSNAs).[9] Electronic cigarettes are far less risky to individual users than cigarettes because they do not result in the inhalation of pyrolyzed chemicals. On the other hand, e-cigarettes and ARPVs, and the e-liquid that is used in them, do not contain any tobacco and are demonstrably less harmful than tobacco-combusting products. FDA should tailor the regulatory requirements for tobacco/nicotine products according to where the product falls on the continuum. The more harmful/riskier the product, the higher the regulatory and paperwork burden should be.

c. E-Cigarettes Provide a Public Health Benefit

In terms of the "public health" (net population) consideration, there is significant evidence that demonstrates that these products (and especially the refillable ARPVs) are overwhelmingly used by adults who have transitioned away from smoking cigarettes to vaping (of course, these products do not claim to be smoking cessation or nicotine replacement products, which would make them drugs, but only recreational-use alternatives to smoking cigarettes). There is little to no evidence that supports that these products are being used as a "gateway" to conventional, combustible cigarettes. Rather, they are being used as a "portal" away from smoking. A recent study in England published in the journal *Addiction* found that smokers trying to quit were substantially more likely to succeed if they used e-cigarettes than over-the-counter therapies such as nicotine patches or gum. Researchers interviewed almost 6,000 smokers who had tried to quit on their own without counseling from a health professional. About a fifth of those who said they were using e-cigarettes had stopped smoking at the time of the survey, compared with about a tenth of people who had used patches and gum.[10]

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[8] *See* R.R. Baker, *et al.*, *The pyrolysis of tobacco ingredients*, J. Anal. Appl. Pyrolysis 71 (2004) 223-311.

[9] *See* Rodgman, A. and Perfetti, T.A. (2009), *The Chemical Components of Tobacco and Tobacco Smoke*, Boca Raton, FL: CRC Press.

[10] *See* Jamie Brown, et. al., *Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study*, Addiction (forthcoming 2014), abstract available online at: http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract.

d. Advanced Refillable Personal Vaporizers Should Not Be Considered "Covered Tobacco Products" Under the Deeming Regulation

Even if we assume, *arguendo*, that e-cigarettes should be regulated under the same regulatory regime as combustible cigarettes, such regime should apply only to cigarette-look-alike products (commonly referred to as "cigalike" devices) and *not* to ARPVs and the refillable e-liquids used in them.[11] Those products should instead be exempted from the meaning of "covered tobacco products," along with premium cigars, under the NPRM"s "Option 2".[12]

ARPVs compare to cigalike devices in many of the same ways that premium cigars compare to cigarettes and little cigars. For example, both products are used by adult connoisseurs and can generally only be found in specialty stores (cigar shops and tobacconists for premium cigars and "vape shops" for ARPV mods and e-liquids). These products are also much more expensive than their cheaper counterparts. ARPVs can cost a few hundred dollars to assemble, significantly more than the typical ready-made cigalike device which, like cigarettes

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[11] Unlike the simple and relatively inexpensive closed-system cigalike e-cigarettes that first entered the market, ARPVs are highly advanced personal vaporizer devices that provide more effective nicotine delivery (and therefore are more likely to keep former smokers from reverting back to cigarettes). These products often contain microprocessors providing additional safety features like over/under-charge protections, short-circuit protections and "smart charging" ability (cell phone technology that stops charging current flow to battery when battery is fully charged). Newer refillable tanks/atomizers do not contain the cartomizer filler material found in cigalikes (which has the potential to melt/char if heated after the e-liquid is consumed). Many newer advanced devices also contain a "boost circuit" which helps to ensure consistent aerosol output by maintaining the heat level (as long as the battery has sufficient charge to activate the boost), as well as offer adjustable airflow features allowing the user to customize their experience and prevent potential "dry puff".

[12] The NPRM proposes two alternatives regarding the scope of the rule: Option 1 would include all cigars as products covered by the proposed regulations and Option 2 would carve out an exception from coverage for "premium cigars." A "premium cigar" would be defined as a cigar that: (1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.

and little cigars, are widely distributed in convenience and dollar stores, where they are more likely to be viewed by children. For this reason, to the extent that e-cigarettes *may* entice some non-smokers to start vaping and/or smoking, the likely culprit will be cigalike devices rather than ARPVs. In this regard, we note that the vast majority of ARPV users are former smokers who, when they were unsatisfied with cigalikes, transitioned to the more advanced products instead of reverting back to combustible cigarettes. APRV users also do not typically engage in "dual use" with cigarettes, because the advanced products are better able to satisfy their cravings. Of course, any hypothetical "gateway" threat posed by cigalike devices must be balanced against the public health benefit those products offer by providing a less harmful alternative for cigarette smokers. Accordingly, because ARPVs provide a clear public health benefit, they should be exempted from the NPRM's coverage, even if cigalike devices are eventually included.

AEMSA will be providing additional information to support these assertions in our general comments to the NPRM, which are currently due to FDA by July 9, 2014. As noted above, however, for these comments on the PRA information collection issues, we assume, *arguendo*, that e-cigarette and e-liquid products will be subject to the Tobacco Control Act requirements once the NPRM is effective.

IV. Paperwork Reduction Act Comments

The NPRM, if allowed to go into effect, will impose on the e-cigarette and refillable e-liquid industry an unprecedented, on-going and burdensome information collection regime. Individually and as a group, the elements of the NPRM information collection mandates described below will unjustifiably and unnecessarily increase the paperwork burdens on all "other tobacco, e-cigarettes, and nicotine product manufacturers," including manufacturers and suppliers of ARPVs and refillable e-liquids. While we recognize that these information collections were not conjured out of thin air, but based on the statutory requirements in the Tobacco Control Act, we believe FDA erred in not using the discretion envisioned by Congress to either exempt ARPVs and refillable e-liquids from meaning of "covered tobacco product," or to tailor the information collections to more appropriately suit the e-cigarette and e-liquid industries, which are very different from traditional tobacco. Thus, for the reasons set forth below, FDA cannot certify, and the OMB cannot approve, these new information collection mandates under the PRA.

The express purpose of the PRA is to "minimize the paperwork burden" imposed by the government and "ensure the greatest possible pubic benefit from and maximize the utility of

information created, collected, maintained, used, shared and disseminated by and for" the government.[13] The legislative history describes the concerns underlying the PRA as follows:

> For the American public, government information often seems to serve either of two quite different purposes. It can be the means by which the dedicated public servant uncovers problems, reaches decisions, enforces laws, delivers services and informs the public. But it also can be the means by which the faceless bureaucrat asks time-consuming or intrusive questions, forces seemingly arbitrary changes in business practices or personal behavior, and imposes significant costs on the economy.

In order to ensure that Congress' goals are met, the PRA and OMB's implementing rules establish a multi-step process for reviewing, analyzing and determining whether the proposed information collections meet several express statutory standards. Specifically, under the PRA and OMB rules, FDA may not conduct or sponsor any "collections of information" unless and until those collections are submitted to and approved by OMB.[14] As a prerequisite to obtaining the required OMB approval, FDA must review the information collections and provide OMB with a certification (including a record supporting such certification) that the information collections in question: (1) are necessary for the proper functioning of the Agency; (2) are not unnecessarily duplicative of information otherwise reasonably accessible to the Agency; (3) have actual (rather than merely theoretical or potential) practical utility as defined by regulation; and (4) reduce, to the extent practicable and appropriate, the burden on respondents.[15] In promulgating the NPRM, FDA has failed to meet the standards mandated by the PRA. It has neither minimized the paperwork, demonstrated the practical utility[16] of the proposed information collections, nor estimated the burden accurately for the e-cigarette and e-liquid industries.

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[13] Pub. L., 104-13, 109 Stat. 163 (1995).

[14] *See generally* 44 U.S.C. § 3507.

[15] *See* 44 U.S.C. § 3506(c)(3)(A), (B), (C).

[16] OMB's implementing regulations define the term "practical utility" as: "[t]he actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third-party or public disclosure) in a useful and timely fashion." *See* 5 C.F.R. § 1320.9.

As set forth below, FDA cannot certify that, with respect to the refillable e-liquid industry, the information collections in the NPRM pass these tests. Considered individually or as a group, FDA's proposed information collections in the rule are at odds with the standards for such certification under the PRA. In particular, FDA's estimates of the burdens imposed by NPRM's information collection requirements are substantially, indeed egregiously, understated. Moreover, the information collections that will apply to the refillable e-liquid industry are, in whole or in part, unnecessary, lacking in practical utility, and otherwise violative of the statutory standards. As such, FDA would be acting in disregard for its statutory obligation if it certified the compliance of these information collections with the PRA.

a. Information Collections Required for the Newly Deemed Tobacco Products

FDA's paperwork burden estimates for the information collection provisions[17] are grossly inaccurate because the Agency's estimate of the number of respondents in the "other tobacco, e-cigarettes, and nicotine product manufacturers," category, as well as the number of such products on the market (that will be subject to the various disclosure and premarket authorization requirements), is underestimated by *orders of magnitude*. We do not believe that these estimates are miscalculations on FDA's part, but rather based on the assumption that most of these small companies will not be able to comply with the burdensome and costly regulations, and thus will be forced to exit the industry. We note, however, that while many of these companies are small, they are entrepreneurial and are continuing to grow, and intend to comply with FDA's regulations. To propose a rule that assumes up to 99.99% of the thriving ARPV and e-liquid companies will be eliminated is obdurate beyond reason. Rather, FDA should use the enforcement discretion envisioned by Congress to either (1) exempt ARPVs and refillable e-

[17] Specifically, in Section IX (A) and (B) of the NPRM, FDA is requesting comment on the information collections for (1) existing OMB-approved burdens for the currently regulated tobacco products (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco) which are being expand to cover the deemed tobacco products, and (2) burdens associated with tobacco products that are subject to the FDCA, including the proposed deemed tobacco products, but that have not yet been approved by OMB. *See* 79 Fed. Reg. at 23,184. We do not address the information collection request in Section IX (C) of the NPRM for "new collections of information that applies only to proposed deemed tobacco products," which pertains to the health warning requirement for *tobacco* products that do *not* contain nicotine (but must still, by definition, contain either tobacco or other tobacco-derived substances). Accordingly, this information collection does not apply to the refillable e-liquid industry, whose products are subject to FDA's authority under the Tobacco Control Act if and only if they contain nicotine derived from tobacco. *See Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C., 2010)).

liquids from the Tobacco Control Act requirements, or (2) impose appropriate regulatory and paperwork requirements tailored to these products.

Furthermore, FDA has indicated that it based these new burden estimates for the proposed deemed tobacco products on the existing OMB-approved collections for the currently regulated tobacco products. Using information related to the existing collections for completely different types of companies and products, however, is inappropriate and does not come close to reflecting the burden these collections will impose on the rapidly growing e-cigarette and refillable e-liquid industries.

More specifically, FDA has estimated that only 140 "other tobacco, e-cigarettes, and nicotine product manufacturers" will register as tobacco product establishments and that 188 companies will submit their product and ingredient lists to the Agency.[18] We have summarized FDA's annual burden estimates for these collections in the following table:

[18] Under Section 905(b) of the Tobacco Control Act, any person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding or processing of a tobacco product must register with FDA the name, places of business, and all establishments owned or operated by that person. Section 905(a)(i) further requires all such registrants to file with FDA a list of all tobacco products being manufactured, prepared, compounded or processed by that person for commercial distribution, along with certain consumer information such as labeling and sample advertisements. Moreover, Section 904(a)(1) requires each such tobacco product manufacturer or importer to submit a list of all ingredients, including tobacco, substances, compounds and additives that are added by the manufacturer to the tobacco product "by brand and by quantity in each brand and subbrand."

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response (hours)	Total Hours
Tobacco Establishment Registration	140	1	140	3	420
Product Listing	188	8.9	1,675	0.75	~~119~~ 1256[19]
Ingredient Listing	188	8.9	1,675	3	5,025

FDA has similarly underestimated the number of such other tobacco product manufacturers that will submit the required health documents (one),[20] attempt to establish the grandfathered status of a product (140),[21] and prepare substantial equivalence reports (140),[22]

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[19] We note FDA appears to have incorrectly indicated that 119 total hours will result from the product listing information collection. This appears to be a typographical error, as 1,675 total annual responses multiplied by an average burden of 0.75 hours results in 1256 total hours. *See* 79 Fed. Reg. at 23,185.

[20] Section 904(a)(4) of the Tobacco Control Act requires each tobacco product manufacturer or importer to submit all documents developed after June 22, 2009 that relate to health, toxicological, behavioral or physiological effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components and additives. FDA states in the proposed rule that "[t]o derive the number of respondents for this provision, FDA assumes that very few of the respondents subject to registration requirements would have health documents to submit." *See* 79 Fed. Reg. at 23,187. To suggest that there may only be *one* "other tobacco, e-cigarette, or nicotine product manufacturer" in the country that would have this type of information is preposterous. As discussed more fully below, FDA has grossly underestimated the number of respondents, particularity with respect to the refillable e-liquid industry.

[21] The Tobacco Control Act provides that tobacco products that were commercially marketed in the United States as of February 15, 2007 are considered grandfathered products not

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requests for exemption from the substantial equivalence requirements (140),[23] and premarket tobacco applications (25).[24] We have summarized FDA's annual burden estimates for these information collections in the following table:

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subject to premarket review. FDA's draft guidance "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007," provides information on what evidence is needed to demonstrate that a product is indeed grandfathered.

[22] Section 905(j)(i) of the Tobacco Control Act permits manufacturers of proposed deemed tobacco products to submit a report to FDA demonstrating that their new tobacco product is substantially equivalent to a product that was on the market as of the Grandfather Date identified in the statute, *i.e.*, February 15, 2007. FDA has based the burdens for this information collection for the newly deemed tobacco products on the existing collection that applies to the currently regulated tobacco products. As noted below, however, AEMSA's position is that FDA should use its enforcement discretion to allow deemed tobacco products that were on the market as of the NPRM publication date (*i.e.*, April 25, 2014) to remain on the market in the future and also to serve as predicate products for SE reports for future products.

[23] Section 905(j)(3) of the Tobacco Control Act and FDA's implementing regulations in 21 C.F.R. § 1107 establish a pathway for tobacco product manufacturers to request exemptions from the substantial equivalence requirements in Section 905(j) of the Act for certain modifications made to their products (hereafter referred to as the Minor Modification Exemption or MME). Specifically, FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines (1) the modification would be a minor modification of a tobacco product sold under the Act, (2) a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health, and (3) an exemption is otherwise appropriate.

[24] Under Section 910 of the Tobacco Control Act, in order to market a new tobacco product (*i.e.*, a tobacco product that was not on the market as of February 15, 2007, or modified in any way since that date), the manufacturer must submit a PMTA and obtain an order from FDA allowing the marketing of that product. FDA estimates that 5,000 hours will be required to obtain a PMTA marketing authorization order assumes 200 hours for writing the application and 4,800 hours of "conducting the necessary scientific investigations." *See* 79 Fed. Reg. at 23,194. This high burden (and associated cost) is apparently why the Agency has estimated that it will only receive 25 PMTAs from manufacturers of other tobacco, e-cigarettes and nicotine products. As discussed below, however, these estimates vastly understate the number of PMTAs that we
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Activity		**No. of Respondents**	**No. of Responses per Respondent**	**Total Annual Responses**	**Average Burden Per Response (hours)**	**Total Hours**
Tobacco Health Document Submission		1	4	4	50	200
Establish Grandfathered Status		140	1.5	210	10	2,100
SE Report	SE Reports; Sections 905(j)(1)(A)(i) and 910(a)	140	2.26	316	180	56,880
	Section 25.40 Environmental Assessment for SE Report	140	2.26	316	12	3,792
MME Request	21 C.F.R. § 1107.1(b); Prepare MME	140	0.5	70	12	840
	21 C.F.R. § 1107.1(c); Prepare additional info for MME	140	0.15	21	3	63

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expect will be filed for e-liquid products alone. FDA is effectively acknowledging that most manufacturers will be driven out of the business by the burden of compliance.

Activity		No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response (hours)	Total Hours
MME Request	Section 25.40 Environmental Assessment for MME	140	0.5	70	12	840
	Section 905(j)(1)(A)(ii)	140	0.75	105	3	315
PMTA	Submitting PMTA	25	1	1	5,000	125,000
	Request CTP Meeting	25	1	1	4	100
	Section 25.40 Environmental Assessment for PMTA	25	1	25	12	300

As discussed below, FDA has grossly underestimated the number of respondents, the number of responses, and the average and total burdens from these proposed information collections.

b. FDA Has Grossly Underestimated the Burdens Imposed By the NPRM

i. FDA' Estimate of the Number of Potential Respondents in the "Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers" Product Category is Egregiously Low

As described above, FDA is proposing a number of information collections intended to apply to the newly deemed tobacco products including electronic cigarettes and their e-liquid components. FDA's proposed information collections are at odds with the standards for such certification under the PRA. In particular, FDA's estimates of the burdens imposed by NPRM's information collection requirements are substantially, indeed egregiously, understated. Specifically, the Agency's estimates of the number of respondents in the "other tobacco, e-

cigarettes, and nicotine product manufacturers," category, as well as the number of products on the market manufactured by these companies, are both off by orders of magnitude. As noted above, however, we do not believe that these estimates are miscalculations on FDA's part, but rather based on the assumption that most of these small companies will be forced to exit the industry because of the high compliance and paperwork burdens associated with the regulatory scheme and information collections that currently apply to the regulated tobacco products (*e.g.*, cigarette, cigarette tobacco, smokeless tobacco and roll-your-own tobacco).

We note, however, that while many of these companies are small, they are entrepreneurial and are continuing to grow, and intend to comply with FDA's regulations. Rather than proposing a rule that assumes up to 99.99% of the thriving ARPV and e-liquid companies will be eliminated, FDA should use the enforcement discretion envisioned by Congress to either (1) exempt ARPVs and refillable e-liquids from the Tobacco Control Act requirements, or (2) impose appropriate regulatory and paperwork requirements tailored to these products.

Moreover, the information collections that the NPRM proposes to apply to the e-cigarette and e-liquid industry are in whole or in part unnecessary, lacking in practical utility, and otherwise violative of the statutory standards. As such, FDA would be acting in disregard for its statutory obligation if it certified the compliance of these information collections with the PRA.

Even if most of these companies end up exiting the industry as FDA supposes, we believe that the estimate that there will be a maximum of 188 respondents to the above information collections does not come close to reality. The e-cigarette industry in the United States has roughly doubled *every year* since the products first started being commercially distributed. Sales in 2008 were approximately $50 million; in 2014 sales are expected to exceed well over $1 *billion*.[25] That value, however, may underestimate the actual size of the e-cigarette industry because it is based on limited monitoring of major sales outlets (*e.g.*, convenience stores), which mainly report sales of cigalike e-cigarette products captured from electronic sales records. Not included in this data are sales from the rapidly growing e-cigarette subcategories of ARPVs and their components (*e.g.*, e-liquids and hardware), that are sold either online or in brick-and-mortar

[25] *See* Nicotine Science and Policy, "New Estimates Double Size of E-Cigarette Market; Increasing Importance of Refillable and Modified Devices" by G. Stimson (March 2014); available online at: http://nicotinepolicy.net/gerry-stimson/1317-wells-fargo-march-2014.

"vape shops."[26] Considering ARPV and e-liquid sales, total e-cigarette sales in the U.S. are expected to be between $2.2 to 3 billion in 2014.[27]

As indicated above, we are in the process of gathering data on the number of these ARPV companies (specifically, e-liquid companies) and unique product formulations presently on the market. We note, however, that, with respect to the refillable e-liquid industry alone, the available evidence indicates that there are at least **5,000** and possibly up to **15,000** individual e-liquid producers in the United States, nearly all of which are small businesses (*i.e.*, less than 350 employees), including vape shops that mix their own products. Specifically, we note that:

- The Smoke Free Alternatives Trade Association, a trade association of representing small and mid-sized businesses in the vapor industry, including vape shops, manufacturers, importers and distributors, has estimated that there are 1,200 e-liquid manufacturers that make their own e-liquid and 15,000 vape shops in the United States (many of whom also mix their own e-liquids), representing over 65,000 jobs. This estimate is based on internal data collected from manufacturer and distributor members, as well as insurance researchers. *See* www.sfata.org.

- Prominent Wall Street Securities Analyst Bonnie Herzog of Wells Fargo estimates that that are 5,000 to 10,000 vape shops in the United States.[28]

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[26] In particular, we note that one potential method of determining the size of the e-liquid market is to calculate the total amount of nicotine being consumed in the country from e-liquids by taking the total amount of USP grade nicotine produced/imported into the country and discounting the amount used in nicotine replacement therapies (NRTs). Based on this and using the average nicotine concentration in e-liquid (of 1.8% or 18 mg/ml), the total volume of nicotine-containing e-liquid consumed in the U.S. may be extrapolated. AEMSA will be submitting more detailed comments and our legal reasoning for this framework in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

[27] *See* Wells Fargo Securities, Equity Research, March 24, 2014, "Tobacco Talk: Vapors/Tanks Driving Next Wave of E-E-Vapor Growth," available online at: http://www.vaporworldexpo.com/PDFs/Tobacco_Talk_Vapors_Tanks_%20March%202014.pdf.

[28] *See* Wells Fargo Securities, Equity Research, April 14, 2014, "Vape Shops – Springing Up Across The Country," available online at: http://www.vaporworldexpo.com/PDFs/Tobacco_%20Vape_Shop_Visit_Apri_2014.pdf.

- The Vapor Search USA online portal, available at http://www.vaporsearchusa.com/, has over 5,000 e-liquid producers throughout the United States listed in its database.

- The Electronic Cigarette Forum (ECF), an online community for e-cigarette consumers and stakeholders (available at http://www.e-cigarette-forum.com/forum/) has nearly 1,700 e-cigarette and e-liquid businesses (including U.S.-based manufacturers and foreign importers) on record.

These estimates are only for the e-liquid industry, and do not include the hundreds, if not *thousands*, of companies that are manufacturing the various hardware components used in ARPVs (*i.e.*, "mod" components including adapters, atomizers, cartomizers, clearomizers, batteries, chargers, tanks, endcaps, tubing, internal microprocessors/motherboards, springs, o-rings, drip-tips/mouth pieces, wicking materials, and other device components such as internal connectors, buttons, casings, gaskets, seals, internal charging circuitry components, etc.).[29] If the NPRM becomes effective, all of these thousands of companies could fall within meaning of "covered tobacco product" manufacturers if those components have any impact on what is being inhaled by the consumer.[30] It is clear that FDA's estimate that only 140 to 188 potential respondents in the entire category of "other tobacco, e-cigarettes, and nicotine product manufacturers" is egregiously off target based on the available evidence, and is based on the assumption that nearly the entire industry, except for only those biggest companies (*i.e.*, "Big Tobacco"), will be eliminated as a result of the regulatory and paperwork burdens in the NPRM.

Accordingly, there is simply no way that FDA can certify that it has accurately estimated the burdens associated with the above information collections for the e-cigarette and e-liquid industries. FDA has erred by completely ignoring the ARPV industry, including manufacturers of refillable liquids and the hardware components of those products. As such, FDA would be acting in disregard for its statutory obligation if it certified the compliance of these information collections with the PRA. Rather than proposing a rule that assumes up to 99.99% of the thriving ARPV and e-liquid companies will be eliminated, FDA should use the enforcement discretion envisioned by Congress to either (1) exempt ARPVs and refillable e-liquids from the

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[29] Further, each of these components can come in many models, sizes or be made from different raw materials.

[30] Please note that AEMSA is preparing more detailed comments about which component parts of ARPVs should be considered covered products and which should be considered "accessories" in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

Tobacco Control Act requirements, or (2) impose appropriate regulatory and paperwork requirements tailored to these products.

ii. FDA' Estimate of the Number of Products in the "Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers" Category Has Also Been Egregiously Underestimated

FDA has also greatly underestimated the total number of e-cigarette, ARPV and e-liquid products that are on the market. With respect to the refillable e-liquid industry alone, there are *tens of thousands* of unique product formulations currently on the market, and growing. Even the smallest e-liquid producers often have dozens of unique product stock keeping units (SKUs), while the largest companies produce hundreds or even thousands of unique formulations.

As noted above, with respect to the Section 904 product and ingredient listing requirements, FDA has estimated that 188 respondents in the "other tobacco, e-cigarettes, and nicotine product manufacturers" category will submit 8.9 responses each, for a total of 1,675 annual responses.

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response (hours)	Total Hours
Product Listing	188	8.9	1,675	0.75	~~119~~ 1256[31]
Ingredient Listing	188	8.9	1,675	3	5,025

These estimates, of course, simply do not reflect the realities of the market and are based on the assumption that most of these small companies will be forced to exit the industry because of the high compliance and paperwork burdens envisioned by the NPRM. With respect to the refillable e-liquid industry alone, even if we conservatively assume that (1) there are only 5,000

[31] As noted above, FDA appears to have incorrectly indicated that 119 total hours will result from the product listing information collection. This appears to be a typographical error, as 1,675 total annual responses multiplied by an average burden of 0.75 hours results in 1256 total hours. *See* 79 Fed. Reg. at 23,185.

e-liquid producers in the country and (2) that each such company has only 20 unique e-liquid formulations, that would mean that there are *at least* 100,000 such products on the market. As these companies continue to grow, we believe many will remain in the industry and comply with FDA's eventual requirements.

As noted above, Section 904(a)(1) of the Tobacco Control Act requires each tobacco product manufacturer or importer to submit a listing of all ingredients that are added by the manufacturer to the tobacco product "by brand and by quantity in each brand and subbrand." In other words, this means that every e-liquid manufacturer will have to submit to FDA a separate list of ingredients *for each of its products*. The collection of such information *in this manner and format* (*i.e.*, separate ingredient listings for each unique e-liquid formulation) would be prohibitively expensive for the majority of the thousands of small e-liquid manufacturers in the country (*each* of whom have anywhere from dozens to hundreds of unique product formulations), and is not necessary for the proper performance of FDA's function. If we assume, *arguendo*, that FDA's estimates that each product listing submission would take 45 minutes to prepare and that each ingredient listing would require 3 hours are accurate, that would result in the following burden for the e-liquid industry:

Activity	**No. of Respondents**	**No. of Responses per Respondent**	**Total Annual Responses**	**Average Burden Per Response (hours)**	**Total Hours**
Product Listing	5,000	20	100,000	0.75	75,000
Ingredient Listing	5,000	20	100,000	3	300,000

This vast amount of information would not only be very difficult and expensive for the many small e-liquid companies to produce for FDA, but would also inundate the Agency with superfluous information that would only slow down the regulatory process. It is clear that the FDA estimated burden associated with the product and ingredient listing requirements for the "other tobacco, e-cigarettes, and nicotine product manufacturers" is egregiously off target based on the available evidence. Again, there is simply no way that FDA can certify that it has accurately estimated the burdens associated with the above information collections. FDA has erred by completely ignoring the ARPV industry, including manufacturers of refillable liquids and the hardware components of those products. As such, FDA would be acting in disregard for its statutory obligation if it certified the compliance of these information collections with the PRA. Rather than proposing a rule that assumes that basically an entire industry will just go out

of business, FDA should use the enforcement discretion envisioned by Congress to either (1) exempt ARPVs and refillable e-liquids from the Tobacco Control Act requirements, or (2) impose appropriate regulatory and paperwork requirements tailored to these products.

1. Alternative Framework for Product and Ingredient Listing Requirements

While we understand that information on what products are on the market and what ingredients are being consumed is important for FDA to have, the Agency should use its enforcement discretion to obtain this data in a less burdensome, more practical manner. Specifically, FDA should use its enforcement discretion to implement an alternative framework for e-liquid companies to comply with Section 904(a)(1), whereby each company would only be required to submit a *single* table of all the ingredients used in its e-liquid products, along with the use-level (concentration) ranges (*i.e.*, minimum and maximum percentages) of those ingredients in their products. A hypothetical example of such a table is as follows:

Ingredient Listing for ABC E-Liquid Company (Hypothetical)			
Ingredient	**Chemical Abstract Services Registry Number (CAS Reg. No.)**	**Minimum Use-Level in All Products (%)**	**Maximum Use-Level in All Products (%)**
Nicotine	54-11-5	0	2.4
Propylene Glycol	57-55-6	0	92
Glycerin	56-81-5	0	9
Distilled Water	7732-18-5	0	2
Ethyl maltol (2-ethyl-3-hydroxy-4-pyrone)	4940-11-8	0	0.2
2-Cyclopenten-1-one	80-71-7 or 930-30-3	0	1
Benzaldehyde, 3,4-dimethoxy-	120-14-9	0	0.5

Ingredient Listing for ABC E-Liquid Company (Hypothetical)			
Ingredient	**Chemical Abstract Services Registry Number (CAS Reg. No.)**	**Minimum Use-Level in All Products (%)**	**Maximum Use-Level in All Products (%)**
Acetic Acid	64-19-7	0	0.3
Furfural	98-01-1	0	1
Ethyl alcohol	64-17-5	0	0.2
Iso-amyl acetate (1-butanol, 3-methyl-, acetate)	123-92-2	0	0.1
Ethyl acetate	141-78-6	0	0.3
Iso-amyl alcohol	123-51-3 or 584-02-1	0	0.5
Acetaldehyde	75-07-0	0	0.2
Ethyl butyrate	105-54-4	0	0.3
Benzaldehyde	100-52-7	0	0.1
Ethyl propionate (propanoic acid, 3-methyl-, acetate)	105-37-3	0	0.4

Furthermore, under this alternative framework, e-liquid companies would be allowed to amend their ingredient list if they added or removed ingredients or increased the maximum concentration of any of their current ingredients in any of their products, rather than submit a new ingredient list specific to the new product. Such a framework would provide FDA with all the information it needs for the proper performance of its function (*i.e.*, information on what substances are being used and at what levels), while dramatically reducing the cost and administrative burden for both e-liquid companies as well as FDA by decreasing the number of

individual ingredient listing submissions. AEMSA will be submitting more detailed comments and our legal reasoning for this framework in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

2. Alternative Framework for Premarket Authorization for New Deemed Tobacco Products

It has not yet been determined whether any e-liquid products were on the market as of February 15, 2007 for use as "predicate products" in SE Reports for such products currently on the market. AEMSA's position, however, is that FDA should use its enforcement discretion to allow deemed tobacco products that were on the market as of the NPRM publication date (*i.e.*, April 25, 2014) to (1) be "preserved" and remain on the market in the future without obtaining FDA premarket authorization (*i.e.*, by way of an SE Report or a PMTA), and (2) serve as predicate products for SE reports for future products. Of course, if such an alternative framework is used, there will be many more respondents filing SE Reports for many more products than has been estimated by FDA.

There are many reasons why it simply does not make sense to apply the February 15, 2007 Grandfather Date to e-cigarettes. Specifically, because of the technological advancements that have been made to these products over the last several years, most of the current products on the market (particularly the ARPVs) do not have the same "characteristics" as the early 2007 models, as that term is defined in the Tobacco Control Act. Moreover, while many of these advancements improve the safety and engineering of the products (*e.g.*, safety advancements made to chargers, short-circuit protections, batteries, e-liquid wicking and quality improvements, etc.), it would be very difficult and expensive to demonstrate that these different characteristics do *not* raise different questions of public health, as is required to demonstrate substantial equivalence. Rather, e-cigarette manufacturers will be incentivized to produce products that are identical to those that may have been on the market on the Grandfather Date, ignoring and excluding the technological advancements that could benefit the public health.

AEMSA will be submitting more detailed comments and our legal reasoning for this framework in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

iii. Internal Costs of Small Businesses Ignored

FDA has also erred by completely ignoring the in-house cost burdens imposed by the proposed information collections. The OMB's regulations define "burden" to mean "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose

or provide information to or for a Federal agency.[32] Internal costs can only be excluded when estimating the burden of an information collection if such costs are related to "usual and customary" activities.[33] In this case, the types of internal costs that will be incurred by e-liquid companies in order to comply with the information collections were not considered by FDA. Indeed, FDA completely ignored the ARPV and refillable e-liquid industries in the NPRM, except to assume that the regulatory and paperwork burdens would be so high that nearly all of the companies in this industry would go out of business. Again, we think that FDA should have at least attempted to use the enforcement discretion envisioned by Congress to either (1) exempt ARPVs and refillable e-liquids from the Tobacco Control Act requirements, or (2) impose appropriate regulatory and paperwork requirements tailored to these products.

As it stands now, the information collections described above are not usual or customary activities for such companies. Rather, the NPRM imposes on these companies detailed information collection requirements as well as the development of complex new information that Congress intended to apply to manufacturers of traditional tobacco-containing products. These new information requirements will result in significant paperwork burdens for the e-liquid industry as well as FDA. For most of the small e-liquid manufacturers in the U.S. the paperwork burdens imposed by these information collections would put them out of business. FDA has clearly recognized this when estimating the number of respondents and products on the market. Accordingly, the information collections should be modified to more appropriately apply to products that only contain tobacco-derived substances, and which do not contain or combust tobacco. AEMSA will be providing alternative regulatory frameworks for such products in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

V. Conclusion

Congress enacted the PRA in relevant part to reduce and minimize the burden Federal paperwork imposes on the public. In issuing the NPRM, FDA has failed to meet the standards mandated by the PRA, as it has neither minimized the paperwork, demonstrated the practical utility of the collections, nor estimated the burdens accurately for e-cigarette and e-liquid companies. Indeed, the Agency's estimation of both the number of e-cigarette and e-liquid

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[32] *See* 5 C.F.R. § 1320.3(b)(1).

[33] OMB's rules state, "[t]he time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (*e.g.*, in compiling and maintaining business records) will be excluded from the 'burden' if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary. *See Id.*, § 1320.3(b)(2).

companies, as well as the number of products, on the market is egregiously low. Rather than attempting to either exempt ARPVs and refillable e-liquids from the Tobacco Control Act requirements, or develop an appropriate regulatory framework and paperwork burdens for these novel products using the enforcement discretion envisioned by Congress, FDA has simply assumed that nearly all of these companies would go out of business before they could ever comply with the requirements.

To reduce the paperwork burdens of the proposed rule, FDA should revise the information collections to more appropriately reflect the realities of e-cigarette and e-liquid companies, and to take into consideration the public health impact of products that only contain tobacco-derived substances (*e.g.*, nicotine), compared to those that contain or combust tobacco. While the Tobacco Control Act broadly defines a "tobacco product" to include substances that are derived from tobacco, products that only contain such tobacco-derived substances should not be regulated in the same manner as products that contain tobacco *per se* (*e.g.*, cigarettes, smokeless tobacco and roll-your-own tobacco). Tobacco-containing products, especially those that are combusted (cigarettes), are the most harmful and dangerous products on the "continuum of risk" and should be treated as such.

On the other hand, e-cigarettes and ARPVs, and the e-liquid that is used in them, do not contain any tobacco and are demonstrably less harmful than tobacco-containing products. In terms of the "public health" (net population) consideration, there is significant evidence that demonstrates that these products (and especially the refillable ARPVs) are overwhelmingly used by adults who have transitioned away from smoking cigarettes to vaping. There is little to no evidence that supports that these products are being used as a "gateway" for non-smokers to conventional, combustible cigarettes. Rather, they are being used as a "portal" away from smoking for current smokers.

One example of an alternative framework for e-liquid companies that FDA should use its enforcement discretion to implement is with respect to the ingredient disclosure requirement in Section 904(a)(1). As described above, rather than requiring e-liquid manufacturers to submit to FDA a separate ingredients list for each of their thousands of unique products (which would be prohibitively expensive for the majority of the thousands of small e-liquid manufacturers in the country), the Agency may consider requiring each company submit a ***single*** table of all the ingredients used in its e-liquid products, along with the use-level ranges (*i.e.*, min % to max %) of those ingredients in all of their products.

FDA should also use its enforcement discretion to allow deemed tobacco products that were on the market as of the NPRM publication date (*i.e.*, April 25, 2014) to remain on the market in the future. Such products (1) would be considered "preserved" and would not be required to submit either a SE Report or a PMTA once the two-year (post effective date) compliance period ends, and (2) could be used as predicate products in future SE Reports. This

would greatly reduce the paperwork burden associated with these premarket authorizations for the thousands of e-cigarette and e-liquid products in the country.

AEMSA will be providing alternative regulatory frameworks such as this in our general comments to the NPRM, which are currently due to FDA by July 9, 2014.

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AEMSA appreciates the opportunity to submit these comments and both FDA's and OMB's continuing efforts to seek input from stakeholders on the Deeming Regulation.

Respectfully submitted,

Lou Ritter
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